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FOX ROTHSCHILD LLP 2000 MARKET STREET PHILADELPHIA, PA 19103			EXAMINER CUTLIFF, YATE KAI RENE	
			ART UNIT 1621	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary

Application No.

10/599,682

Applicant(s)

ISSBERNER ET AL.

Examiner

YATE' K. CUTLIFF

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 16, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 - 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 3 – 5 and 11 - 21 are pending.
Claims 1, 2 and 6 - 10 have been canceled.
Claims 3-5 and 11-21 are rejected.

Response to Amendment

2. The amendment to claims 1-5, 11 and new claim 21, submitted March 16, 2009 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments, see pages 6 - 11, filed march 16, 2009, with respect to the rejection(s) of claim(s) 3 - 20 under 35 U.S.C. 103(a) have been fully considered and are persuasive in view of the amendments and cancellation of claims 6 - 10. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lindner (US 4,332, 702), Memita et al. (US 6,939,980), Miranol Chemical Co. (EP 0163806 A1) (Miranol 1), Sakurai et al. (US 4,113,635), Barth et al. 9US 2,441,555), Burrell et al. (2,427,255), Bauer et al. (WO 2003/028690A), Miranol Chemical Co. (EP 0151992 A2)(Miranol 2), and Plough, Inc. (EP 0179416), as set out below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3 - 5, and 11-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). Further, that the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

6. Claims 3 - 5, 11 as amended and new claim 21 include the phrase: "fatty acid-containing component". This language broadens the coverage of the claim to include fatty acids and components other than fatty acids. Applicant states that in claims 3-5 and 11 the amendment the phrase: "fatty acid-containing component", was added for clarity. However, the Examiner can not find support for this limitation in the body of the originally filed Application.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindner (US 4,332, 702) in view of Memita et al. (US 6,939,980: WO 2002/22548) and further in view of Miranol Chemical Co. (EP 0163806 A1) (Miranol 1).

11. The rejected claim covers a fatty acid ester mixture of pentaerythritol, a pentaerythritol oligomer, or mixtures thereof, wherein the fatty acid component is a mixture containing from about 40% to about 50% by weight of a C16 fatty acid and from about 45% to about 55% by weight of a C18 fatty acid, and wherein the ester contains less than 0.3% by weight C17 fatty acid-containing component and has a melting point of at least 30°C.

Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid-containing component groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid-containing component. As such, since the claimed fatty acid ester of pentaerythritol can be free of C17 fatty acid-

containing component the claim is anticipated by the Lindner reference. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see *National Research Development Corporation v. Great Lakes Carbon Corporation, et al.*, 188 USPQ 327 (D. Del. 1975), 410 F. Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30°C would fall within the scope of the claim.

12. Lindner discloses a partial ester of pentaerythritol, in column 2, lines 13-20 wherein the fatty acid components overlap with Applicant's claimed fatty acid range. Further, Lindner states that these esters are known to be useful as lubricants. (see column 2, lines 8-9).

The difference between Lindner and the claimed ester is: the fatty acid ester mixture having a melting point of at least 30°C; and a fatty acid ester of a pentaerythritol oligomer.

However, Memita et al. discloses a process for producing esters by reacting carboxylic acids having 5 to 30 carbon atoms with polyvalent alcohols like pentaerythritol, dipentaerythritol (pentaerythritol oligomer) and tripentaerythritol (pentaerythritol oligomer). (see abstract, column 2, lines 47 - 65 & column 3, lines 21-32). The products of Memita et al. are known to be useful in a wide range of fields such as cosmetics, pharmaceutical preparations, foods, electronic equipment, printing and lubricants, to mention a few. (see column 1, lines 14-16). The process of Memita et al.

can produce wax esters having a small content of low volatile substances such as a hydroxy group. (see column 5, lines 46 – 50). Examples 1 and 2, along with comparative Examples 1 and 2, disclose the process of producing the esters. (see columns 5, 6 and 7). In Table 1 the mixed ester of Example 2 is shown to have a melting point of 67.7°C, with the mixed ester of Comparative Example 2 having a melting point of 63.4°C.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). In this instance the temperature of “at least 30°C” has been interpreted to mean the minimum melting temperature, which means that the mixture could melt at temperatures above 30°C. The Memita et al. references teaches melting point for mixtures slightly above 30°C”, however, based on the claim as interpreted Memita’s melt temperatures overlaps with any of Applicant’s claimed ester mixtures having melting points above 30°C. Thus, Applicant’s temperature range is considered the results of routine experimentation.

Further, it would have been obvious to one of ordinary skill in the art to obtain a fatty acid ester mixture of pentaerythritol as shown by the disclosure of Lindner, because mixtures of C16 and C18 fatty acids can be easily prepared by the process

taught in Memita et al. The motivation for the mixture is stated in Memita et al. where it is stated that esters are used in a wide range of fields.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

13. With regard to the fatty acid ester mixture of pentaerythritol oligomer, Miranol 1 disclosed that random mixtures of oligomers of pentaerythritol can be used in cosmetics and lubricants (see page 1, abstract & page 2, lines 30-34). The products of the process of Miranol 1 use fatty acids of palmitic (C16) and stearic (C18) acid. Miranol 1 is silent with regards to the melting temperature of the acids they prepared, however, they prepare random mixtures using fatty acid types identical to the types identified by Memita et al. Thus, since the esters of Memita et al. have melting points of 40° to 100°C and include esters prepared using dipentaerythritol (pentaerythritol oligomer) and tripentaerythritol (pentaerythritol oligomer) being reacted with fatty acids that can be palmitic acid and stearic acid, one skilled in the art would presume that these temperature ranges would apply to the esters of Miranol 1.

In light of the fact that fatty acid ester mixtures of pentaerythritol oligomers as taught by Miranol 1, are obtained by known reaction processes, and the melting points overlap with the melting points of Memita et al., it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to obtain the claimed mixtures in the claimed fatty acid weight percentages by that disclosed process by

operator election of the starting fatty acid mixture and controlling the molar amount of acid to alcohol. (see page 4, lines 6 - 19).

Thus, in light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common senses.

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindner (US 4,332, 702) in view of Memita et al. (US 6,939,980: WO 2002/22548) and further in view of Miranol Chemical Co. (EP 0163806 A1) (Miranol 1).

15. The rejected claim covers a fatty acid ester mixture of pentaerythritol, a pentaerythritol oligomer, **or** mixtures thereof, wherein the fatty acid component has 6 to 22 carbon atoms, and wherein the ester contains less than 0.3% by weight C17 fatty acid-containing component and has a melting point of at least 30°C with a percentage content of (a) from about 10% to about 25% by weight monoesters, (b) from about 25% to about 40% by weight diesters, and (c) from about 30% to about 45% by weight triesters.

Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those

of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid-containing component groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid-containing component. As such, since the claimed fatty acid ester of pentaerythritol can be free of C17 fatty acid-containing component the claim is anticipated by the reference. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see *National Research Development Corporation v. Great Lakes Carbon Corporation, et al.*, 188 USPQ 327 (D. Del. 1975), 410 F. Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30°C would fall within the scope of the claim.

16. Lindner discloses an ester of pentaerythritol, in column 2, lines 21-25 wherein the mixture has a percentage content of monoester, diester and triester overlap with Applicant's claimed ester content.

The difference between Lindner and the claimed ester is: the fatty acid ester mixture having a melting point of at least 30°C; and a fatty acid ester of a pentaerythritol oligomer.

However, Memita et al. discloses a process for producing esters by reacting carboxylic acids having 5 to 30 carbon atoms with polyvalent alcohols like

pentaerythritol, dipentaerythritol (pentaerythritol oligomer) and tripentaerythritol (pentaerythritol oligomer). (see abstract, column 2, lines 47 - 65 & column 3, lines 21-32). The products of Memita et al. are known to be useful in a wide range of fields such as cosmetics, pharmaceutical preparations, foods, electronic equipment, printing and lubricants, to mention a few. (see column 1, lines 14-16). The process of Memita et al. can produce wax esters having a small content of low volatile substances such as a hydroxy group. (see column 5, lines 46 – 50). Examples 1 and 2, along with comparative Examples 1 and 2, disclose the process of producing the esters. (see columns 5, 6 and 7). In Table 1 the mixed ester of Example 2 is shown to have a melting point of 67.7°C, with the mixed ester of Comparative Example 2 having a melting point of 63.4°C.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). In this instance the temperature of "at least 30°C" has been interpreted to mean the minimum melting temperature, which means that the mixture could melt at temperatures above 30°C. The Memita et al. references teaches melting point for mixtures slightly above 30°C", however, based on the claim as interpreted Memita's melt temperatures overlaps with any of Applicant's claimed ester mixtures

having melting points above 30°C. Thus, Applicant's temperature range is considered the results of routine experimentation.

Further, it would have been obvious to one of ordinary skill in the art to obtain a fatty acid ester mixture of pentaerythritol that include a mixture of partial esters that have varying percentages of monoester, diester and triester as shown by the disclosure of Lindner, because this type of mixture can be easily prepared by the process taught in Memita et al., which teaches partial hydrogenation of esters. The motivation for the mixture is stated in Memita et al. where it is stated that esters are used in a wide range of fields.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

17. With regard to the fatty acid ester mixture of pentaerythritol oligomer, Miranol 1 disclosed that random mixtures of oligomers of pentaerythritol that can be used in cosmetics and lubricants (see page 1, abstract & page 2, lines 30-34). The products of the partial hydrogenation process of Miranol 1 uses fatty acids of lauric (C12), myristic (C14), palmitic (C16) and stearic (C18) acid. Miranol 1 is silent with regards to the melting temperature of the acids they prepared; however, they prepare random mixtures using fatty acid types identical to the types identified by Memita et al. Thus, since the esters of Memita et al. have melting points of 40° to 100°C and include esters prepared using dipentaerythritol (pentaerythritol oligomer) and tripentaerythritol (pentaerythritol

oligomer) being reacted with fatty acids that can be of lauric (C12), myristic (C14), palmitic (C16) and stearic (C18) acid, one skilled in the art would presume that mono-, di- and triesters prepared with these temperature ranges applying to the esters of Miranol 1.

In light of the fact that fatty acid ester mixtures of pentaerythritol oligomers as taught by Miranol 1, are obtained by known reaction processes, and the melting points overlap with the melting points of Memita et al., it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to obtain the claimed mixtures in the claimed fatty acid weight percentages by that disclosed process by operator election of the starting fatty acid mixture and controlling the molar amount of acid to alcohol. (see page 4, lines 6 - 19).

Thus, in light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common senses.

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (US 4,113,635).

19. The rejected claim covers a fatty acid ester mixture of pentaerythritol, a pentaerythritol oligomer, or mixtures thereof, wherein the fatty acid component has 6 to

22 carbon atoms, and wherein the ester contains less than 0.3% by weight C2 fatty acid-containing component and has a melting point of at least 30°C with a percentage content of (a) from about 12% to about 19% by weight monoesters, (b) from about 25% to about 35% by weight diesters, (c) from about 30% to about 40% by weight triesters, and (d) from about 6 to about 11% by weight tetraesters.

Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid-containing component groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid-containing component. As such, since the claimed fatty acid ester of pentaerythritol can be free of C17 fatty acid-containing component the claim is anticipated by the Lindner reference. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see National Research Development Corporation v. Great Lakes Carbon Corporation, et al., 188 USPQ 327 (D. Del. 1975), 410 F. Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one

thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30°C would fall within the scope of the claim.

20. Sakurai et al. discloses lubricant compositions of a solid film type, with partial esters of pentaerythritol with fatty acids as the chief constituents, rust-preventative, lubrication-improving agents, surface active agents, etc., having melting points of 30 to 60°C. (see column 1, lines 11-23). The fatty acids used to produce the corresponding partial esters by the reaction with pentaerythritol are from animal oil, vegetable oils, and straight chain fatty acids i.e. capric, undecanoic, lauric, myristic, palmitic, stearic and olefinic fatty acids. (see column 3, lines 40-51). Also, it is stated that most of the partial esters of pentaerythritol of a fatty acid have melting points of less than 60°C. (see column 3, lines 26-27). Example 3 discloses pentaerythritol esters that are 20% monoester, 30% diester, 40% triester and 10% tetraester. According to the results in Table 3 the lubricant of Example 3 exhibited satisfactory results for Applicant's intended purpose. The ranges in Examples 3 overlap Applicant's claimed ranges for the diester, triester and tetraester, and are close to the monoester range.

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In this instance the fatty acid component of the prior art encompasses the fatty acid content of Applicant's claimed mixture.

Further, the difference between Sakurai et al. and the claimed inventions is that it does not teach the invention with particularity so as to amount to anticipation (See M.P.E.P. § 2131: "[t]he identical invention must be shown in as complete detail as is

contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipse dixit* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)).

However, based on the above, *Sakurai et al* teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill in the art. (see M.P.E.P. § 2143).

21. Lastly, It is well established that consideration of a reference is not limited to the preferred embodiment or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. (in *re Boe*, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In *re Lamberti*, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In *re Fracalossi*, 681 F.2d 792, 794), 215 USPQ 569, 570 (CCPA 1982); In *re Kaslow*, 707, F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983)).

22. Claims 11-20 rejected under 35 U.S.C. 103(a) as being unpatentable over *Barth et al.* (US 2,441,555) and *Burrell et al.* (2,427,255); in view of *Miranol Chemical Co.* (EP 0163806 A1) (*Miranol 1*), *Plough, Inc.* (EP 0179416), *Miranol Chemical Co.* (EP 0151992 A2) (*Miranol 2*), *Bauer et al.* (WO 2003/028690A; US 2004/0258721) and *Sakurai et al.* (US 4,113,635).

23. The rejected claims covers, *inter alia*, a cosmetic and/or pharmaceutical composition comprising an ester formed by esterification of pentaerythritol, a

pentaerythritol oligomer, or mixtures thereof with C6-22 fatty acids, wherein the ester contains less than 0.3% by weight C17 fatty acid-containing component and has a melting point of at least 30°C. Dependent claims 12-19 disclose additional components of the cosmetic or pharmaceutical composition. Dependent claim 20 further limits the cosmetic composition.

Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In *re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid-containing component groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid-containing component. As such, since the claimed fatty acid ester of pentaerythritol can be free of C17 fatty acid-containing component the claim is anticipated by the Lindner reference. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see *National Research Development Corporation v. Great Lakes Carbon Corporation, et al.*, 188 USPQ 327 (D. Del. 1975), 410 F. Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one

thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30°C would fall within the scope of the claim.

24. However, Barth discloses a process for preparing mixed esters using pentaerythritol and polypentaerythritols (pentaerythritol oligomer) from the reaction of pentaerythritol and polypentaerythritols with higher fatty acids. The fatty acids that provide the long chain fatty acid radical are fatty acids with 10 or more carbon atoms per molecule (C10 to C22) (see column 3, lines 54-55 & column 4, lines 17-27 & Example 1). Further, in Table 1 all of the ester products are shown to have melting points between 36 and 38°C. Also, the esters of Barth have lubricating properties. (see column 1, lines 8-11 & column 3, lines 59-63).

Further, Burrell et al. discloses a process for the production of artificial waxes that can be produced by esterifying pentaerythritol or a polypentaerythritol with monobasic saturated fatty acids containing 10 to 22 or more carbon atoms per molecule. (see column 1, lines 45-49). It is stated that mixtures of pentaerythritol and polypentaerythritols may be used to esterify the fatty acid constituents of the waxes. In Burrell et al. the polypentaerythritols generally produce slightly harder waxes with slightly higher melting points than the waxes produced from the pentaerythritol. Also, in Burrell, saturated fatty acids are the preferred acid ingredients and mixtures thereof; i.e. capric, myristic, lauric, stearic, palmitic ... (see column 3, lines 14-25). The mixture can be for example 70% palmitic acid and 30% stearic acid. (see column 3, lines 37-39). Further, Burrell et al. states that a suitable proportion of fatty acid is that required by stoichiometric considerations, but a greater or lesser amount may be used as desired.

Also, the stoichiometric amounts are easily determined by the usual analyses for carboxyl and hydroxyl groups, for example by determining the acid number and acetyl value. (see column 3, lines 49-67). The waxes prepared by the process of Burrell et al. can be used as lubricants. (see column 9, line 68).

The Barth and Burrell et al. references differ from the claimed composition in that they do not state that the ester formed can be included in a cosmetic or pharmaceutical; that the cosmetic or pharmaceutical can have a wax component, a non ionic surfactant, an oil component; and contain mono-, di- and tri- ester in the mixture.

25. However, with regard to the use of the products types taught by Barth and Burrell et al. in cosmetics or pharmaceutical compositions, Miranol 1 discloses a process for preparing esterified pentaerythritol oligomers and their use in cosmetics and toiletries and as lubricants and corrosion inhibitors. (see page 1, lines 5-8; page 5, lines 7-18). With the products of Miranol 1 the degree of esterification of the pentaerythritol oligomer is normally in the range of 12.5 to 62.5%, preferably in the range of 25 to 50%. (see page 4, lines 10-12). Applicant's degree of esterification based on claim 13 ranges from 40 to 95%. Further, Miranol 1 uses fatty acids having from 6 to 18 carbon atoms. (see page 4, lines 15-17). The composition of Miranol 1 may contain 0.5 to 20% of the oligomer mixture. (see page 5, lines 19-20). The cosmetic formulations may contain mono esters of glycerol with fatty acids 12-20 (page 5, lines 28-29), water (page 6, line 4), fatty alcohols (page 6, line 26) and a wax (page 7, lines 7 – 8). Also, Applicant is directed to Examples 8-12.

Additionally, with regard to the use of products of Barth and Burrell et al. references in cosmetics or pharmaceutical compositions, Plough discloses a long ware cosmetic that uses pentaerythritol tetra (C20-C24) aliphatic hydrocarbon carboxylate. (see page 1, paragraph 3). The composition of Plough includes waxes (page 3, para. 3), cetyl alcohol (page 3, last line), sucroglycerides (see page 4, para. continued from page 3), oils (page 4, para. 1), and nonionic surfactants (page 5, para. 6). Applicant is directed to Examples I—VI.

Furthermore, with regard to the use of the products the type produced by the process of Barth and Burrell et al. in cosmetics or pharmaceutical compositions, Miranol 2 discloses partial esters of tripentaerythritol from the esterification of tripentaerythritol with lauric, myristic, palmitic, stearic and oleic acids. Preparation 7 discloses a product where the fatty acid is a mixture of palmitic and stearic acid which produced a hard wax-like solid. Data with regard to Preparations 2-6 show that these preparations are incorporated into cosmetic compositions. These preparations were added to cosmetic compositions that included fatty alcohol, water, oil and wax. (see Examples 1 - 17).

Lastly, Bauer et al. discloses a cosmetic or dermatological stick that includes pentaerythryl tetraisoosterate, lanolin oil, jojoba oil, bees wax as some of the ingredients. Applicant is directed to the disclosure of Examples 93, 94 and 96 on page 46.

For the reasons set forth above in paragraphs 20 - 22, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare cosmetic and/or pharmaceutical composition comprising an ester by the esterification of pentaerythritol as disclosed by the teachings of Barth et al. and Burrell

et al. and prepare mixtures of the esters as suggested by Miranol 1; then mix those ester mixtures with other components known to be useful in the cosmetic and/or pharmaceutical industry as suggested by Plough, Miranol 2, Bauer et al and Sakurai et al.

Therefore, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

26. With regard to the ratio of mono-, di- and tri- ester in the ester mixture, Sakurai et al. discloses that esterification of fatty acids with pentaerythritol preferably produce mono-, di- and tri substituted esters and the partial esters are useful in industry. Also, the teaching of Burrell et al. states that the stoichiometric amount of fatty acid used in the esterification may be adjusted as desired. (see column 3, lines 49-59). For these reasons it would have been in the purview of one of ordinary skill in the art to modify the amount of fatty acid used in the esterification reaction to produce a mixture with the desired ester ratio.

Applicant's claim is to a cosmetic and/or pharmaceutical composition comprising esters of pentaerythritol produced by an esterification process. The combination of Barth et al. and Burrell et al.; in view of Miranol 1, Plough, Miranol 2, Bauer et al. and Sakurai et al. suggest the process for preparing esters of pentaerythritol and/or the

mixtures thereof, and the esters having use in industry and one of those industries being the cosmetics industry.

Applicant is reminded that claim 11 is claimed in a Product-by-Process format. The PTO takes the following position with respect to Product-by-Process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garner, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and

the prior art product. In re Marosi, 710 F.2d 798,802,218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 102

27. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

28. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Sakurai et al. (US 4,113,635).

29. The rejected claim covers a fatty acid ester mixture of pentaerythritol, wherein the fatty acid contains 6 to 22 carbon atoms, and wherein said ester mixture contains less than 0.3% by weight of C17 fatty acid-containing component, and has a melting point of at least 30°C.

30. Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid-containing component groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid-containing component. As

such, since the claimed fatty acid ester of pentaerythritol can be free of C17 fatty acid-containing component the claim is anticipated by the reference. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see *National Research Development Corporation v. Great Lakes Carbon Corporation, et al.*, 188 USPQ 327 (D. Del. 1975), 410 F.Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30°C would fall win the scope of the claim.

31. Sakurai et al. discloses lubricant compositions of a solid film type, with partial esters of pentaerythritol with fatty acids as the chief constituents, rust-preventative, lubrication-improving agents, surface active agents, etc., having melting points of 30 to 60°C. (see column 1, lines 11-23). The fatty acids used to produce the corresponding partial esters by the reaction with pentaerythritol are from animal oil, vegetable oils, and straight chain fatty acids i.e. capric, undecanoic, lauric, myristic, palmitic, stearic and olefinic fatty acids. (see column 3, lines 40-51). Also, it is stated that most of the partial esters of pentaerythritol of a fatty acid have melting points of less than 60°C. (see column 3, lines 26-27).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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